of a water-insoluble polymer and a modifying agent. The transitional phrase "consisting essentially of" limits the scope of the claim to the specified materials "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). Accordingly, the semipermeable membrane of the claimed invention does not include additional ingredients that would affect the water-insoluble nature of the membrane and its ability to disrupt.

Support for new claim 27 is provided by original claim 8. Applicants submit that no new matter has been introduced by any of the claim amendments.

II. The Claimed Invention

A summary of the claimed invention and a description of its delayed release behavior appear on pages 2-3 of Applicants' previous communication transmitted by facsimile on June 10, 2002.

III. Claim Rejection – 35 U.S.C. §103(a)

The rejection of claims 1, 3-20 and 23-26 under 35 U.S.C. §103(a) as allegedly being unpatentable over Makino et al. (EP 0237 200) ("Makino") has been maintained.

Claim 1 has been amended to clarify that the polymeric make-up of the semipermeable membrane is limited to water-insoluble polymers. Thus, the transitory phrase "consists essentially of", as it defines the semipermeable membrane, excludes additional ingredients in the composition that would alter the characteristics and properties of the membrane. The semipermeable membrane must be able to disrupt. Advantageously, the dosage form comprising a core material coated with the semipermeable membrane does not require an enteric coating.

In contrast, Makino provides a generic list of examples of coating agents, including both water soluble and water-insoluble polymers, without any disclosure or direction with respect to the suitability of any of the coatings for a specific purpose. Thus, Makino does not provide any suggestion that it would have been possible to coat an acid labile substance such as omeprazole with water-soluble and/or water-insoluble polymers to formulate a dosage form that is not enteric coated. Therefore, notwithstanding the disclosure by Makino of ethylcellulose as one of the possible water soluble and water-insoluble polymers for coating omeprazole (See, e.g., page 8, lines 34-41), there is no suggestion that an omeprazole dosage form could be prepared without an enteric coating. Even though the Examiner alleges that ethlycellulose may inherently provide a delayed release, ***there is no suggestion by Makino that an omeprazole core could be coated with a water-insoluble coating agent to provide a dosage form without an enteric coating***.

Applicants' position is supported by the Examples of Makino which are directed to the preparation of a dosage form and the application of an enteric coating. Examples 1-6 and 8 relate to the preparation of a dosage form, i.e., a granule. In accordance with Examples 7 and 9, the granule of Example 3 and 8, respectively, are layered with an enteric coating. Moreover, claim 9 of Makino is expressly directed to an enteric coated pharmaceutical composition.

It is submitted, therefore, that Makino does not suggest coating an omeprazole core with a water-insoluble coating agent to prepare a dosage form without an enteric coating. Makino comports with and validates the conventional pharmaceutical practice of applying an enteric coating layer to omeprazole.

For all of the foregoing reasons, withdrawal of the rejection based on Makino is requested.

IV. Claim Rejection – 35 U.S.C. §103(a)

Claims 1, 3-20 and 23-26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over US 5,817,338 to Bergstrand et al. ("Bergstrand").

Bergstrand is directed to a multiple unit formulation comprising multiple pellets or granules of omeprazole. Each pellet or granule is individually covered with at least one enteric coating layer (See claim 1). As such, the scope of Bergstrand corresponds to the background of the invention which provides that "[a] pharmaceutical oral dosage form of omeprazole is best protected from contact with acidic gastric juice by an enteric coating layer". (col. 1, lines 59-61). In fact, the entirety of Bergstrand relates to the preparation of individually enteric coated layered units which meet the requirements on enteric coated articles defined in the United States Pharmacopeia (See claim 2).

In contrast, the claimed dosage form of omeprazole expressly excludes an enteric coating. Therefore, when considered in its entirety, Bergstrand does not and cannot suggest the claimed invention. Bergstrand provides that talc may be included in an ***optional*** separating layer. The separating layer separates the core material from the enteric coating layer (col. 5, lines 65-67). Accordingly, notwithstanding the disclosure by Bergstrand of talc as a material for the optional separating layer, Bergstrand requires an enteric coating layer. The required enteric coating layer represents a teaching away from the claimed invention which expressly excludes an enteric coating.

For all of the forgoing reasons, it is submitted that Bergstrand does not suggest the claimed invention or provide any motivation to prepare an omeprazole dosage form having no enteric coating. Withdrawal of the rejection based on Bergstrand is requested.

CONCLUSION

Applicants have made a good faith attempt to respond to the Office Action. It is respectfully submitted that claims 1, 3-20 and 23-27 are in condition for allowance, which action is earnestly solicited.

Any fee due in connection with this response should be charged to Deposit Account No. 23-1703.

Dated: October 14, 2002

Respectfully submitted,

Andrew Fessak

Andrew Fessak
Reg. No. 48,528
Agent for Applicants

Customer No. 07470
White & Case LLP
Agent Direct Dial: (212) 819-8437

Amended claims 1 and 20 showing insertions and deletions:

1. (Twice amended) An oral pharmaceutical dosage form comprising a core material coated with a semipermeable membrane, wherein:

the core material comprises an active ingredient selected from the group consisting of omeprazole, an alkaline salt thereof, *S*-omeprazole and an alkaline salt thereof, one or more alkaline additives, one or more swelling agents, and optionally pharmaceutically acceptable excipients;

the membrane consists essentially of [comprises] a water-insoluble polymer and a modifying agent and is able to disrupt; and

the dosage form is not enteric coated.

20. (Twice amended) A process for the manufacture of a dosage form as defined in claim 1, comprising forming the [a] core material [comprising an active ingredient selected from the group consisting of omeprazole, an alkaline salt thereof, *S*-omeprazole and an alkaline salt thereof, one or more alkaline additives, one or more swelling agents, and optionally pharmaceutically acceptable excipients,] and coating the core material with the [a] semipermeable membrane, wherein the dosage form has no enteric coating.